

WHAT IS CLAIMED IS:

- 59
C27
- 50
an
1. A device for collection of breast duct fluid and detection of breast cancer or precancer comprising:
a probe of a diameter sufficiently small to penetrate a breast duct having a distal portion capable of contacting an interior lumen of a breast duct, wherein said distal portion can contact and retrieve a sufficient sample of the breast duct fluid for analysis, said probe unattached to a fluid source or lumen.
 2. A device as in claim 1, wherein the distal portion comprises an absorbent material that can absorb breast duct fluid.
 3. A device as in claim 1, wherein the distal portion comprises a collection portion that can collect the breast duct fluid it contacts.
 4. A device as in claim 3, wherein the collection portion is tubular.
 5. A device as in claim 3, wherein the collection portion extends some of the distance of the probe.
 6. A device as in claim 1, wherein the distal portion comprises a surface having molecules affixed that bind an agent in the ductal fluid it contacts.
 7. A device as in claim 1, wherein the distal portion comprises a means to measure a quality of the ductal fluid *in situ*.
 8. A device as in claim 7, wherein the quality comprises an indicia selected from the group consisting of cell size, cell density, nuclear size, nucleoli size, and chromatin coarseness.
 9. A device as in claim 1, wherein the distal portion comprises a MEMS capable of detecting *in situ* a quality of the ductal fluid.
 10. A device as in claim 9, wherein the quality comprises a marker.
 11. A device as in claim 1, further comprising a coating of an anesthetic on the exterior of the probe.
 12. A device as in claim 1, wherein the probe is rigid before entry into the breast duct, and flexible upon residence in the duct.
 13. A device as in claim 1, wherein the probe comprises a shape memory material.
 14. A method of collection and analysis of breast duct fluid and detection of breast cancer or precancer comprising:

inserting a probe comprising a distal portion that can attract or collect breast duct fluid and contents; and
collecting a sample of ductal fluid into the distal portion.

15. A method as in claim 14, further comprising analyzing the sample of ductal fluid collected by the distal portion of the probe.

16. A method as in claim 14, further comprising removing the probe from the breast duct and analyzing the sample of ductal fluid collected or attracted by the distal portion.

17. A method as in claim 14, wherein analyzing comprises contacting the distal portion comprising ductal fluid with a reagent.

18. A method as in claim 14, wherein analyzing comprises cytological analysis of ductal epithelial cells.

19. A method as in claim 14, wherein analyzing comprises detection of a marker.

20. A method as in claim 14, wherein analyzing comprises measuring a quality of the ductal fluid or ductal cells in situ.

21. A method as in claim 14, wherein collecting comprises a waiting period with the probe in the duct for a period of time in a range from about a few seconds to a few weeks.

22. A system of collection and analysis of breast duct fluid and detection of breast cancer or precancer comprising:

a device comprising a probe for accessing a breast duct having a distal portion for collecting or attracting ductal fluid and/or ductal cells;
reagents for contacting the distal portion for detection of a marker or analysis of the ductal fluid sample, and
instructions for use of the system to diagnose breast cancer or precancer in a breast duct.

23. An article for collection of breast duct fluid and detection of breast cancer or precancer comprising:

a receiving unit of a sufficient dimension to isolate a breast duct opening on a nipple surface, wherein said unit can contact a bead of ductal fluid on the nipple surface at the ductal orifice after nipple aspiration of said nipple.

24. The article as in claim 23, wherein the unit can absorb the aspirated ductal fluid from the nipple surface for analysis.

25. A method of collection and analysis of breast duct fluid and detection of breast cancer or precancer comprising:

contacting a ductal orifice having a bead of ductal fluid on a nipple surface with a receiving unit of a sufficient dimension to isolate the ductal orifice, whereupon said unit absorbs the ductal fluid for analysis.

add a²>

109220" 66421560